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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/084,453	02/28/2002	Lingiu Cao	219425US0	4985
	7590 09/22/2004		EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			TRAN. THAO T	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/084,453	CAO ET AL.				
Office Action Summary	Examiner	Art Unit				
	Thao T. Tran	1711				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR RITHE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 Cf after SIX (6) MONTHS from the mailing date of this communication  - If the period for reply specified above is less than thirty (30) days,  - If NO period for reply is specified above, the maximum statutory properties to reply within the set or extended period for reply will, by some and the properties of the properti	ON. FR 1.136(a). In no event, however, may a replyon. a reply within the statutory minimum of thirty (3 eriod will apply and will expire SIX (6) MONTH statute cause the application to become ARAN	y be timely filed  30) days will be considered timely.  S from the mailing date of this communication.				
Status						
<ul> <li>1) Responsive to communication(s) filed on 2</li> <li>2a) This action is FINAL. 2b)</li> <li>3) Since this application is in condition for all closed in accordance with the practice und</li> </ul>	This action is non-final.  owance except for formal matters					
Disposition of Claims						
4)  Claim(s) 1-12 and 14-21 is/are pending in 4a) Of the above claim(s) is/are with 5)  Claim(s) is/are allowed. 6)  Claim(s) 1-12 and 14-21 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction are	ndrawn from consideration.					
Application Papers						
9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the con 11) The oath or declaration is objected to by the	accepted or b) objected to by the drawing(s) be held in abeyance. rrection is required if the drawing(s)	See 37 CFR 1.85(a). s objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the priority docum application from the International But * See the attached detailed Office action for a	nents have been received. nents have been received in Appl priority documents have been rec reau (PCT Rule 17.2(a)).	ication No reived in this National Stage				
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB, Paper No(s)/Mail Date		nary (PTO-413) nil Date nal Patent Application (PTO-152)				

#### **DETAILED ACTION**

### Election/Restrictions

- 1. Upon further consideration, the Restriction requirement presented in the Office action of June 24, 2004 has been withdrawn.
- 2. Claims 1-12 and 14-21 are currently pending in this application. Claim 13 has been canceled.

## Claim Objections

3. Claim 9 is objected to because of the following informalities: it is preferred to change "obtainable", line 2, to --obtained--. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

4. Claims 10-12, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because the claim is directed to a product; however, the claim does not convey what the product comprises. Instead, the claim recites a method of producing the product. Applicants are required to recite positive limitations for the product.

## Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 8-12, and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Margolin et al. (US Pat. 6,359,118).

Margolin teaches crosslinked enzyme (glycoprotein) aggregates (crystals) and a method of preparing (see abstract); the method comprising providing a plurality of enzyme molecules (glucose oxidase); aggregating the enzyme molecules by a precipitating agent (polyethylene glycol) (see col. 17, ln. 51-52; Example 2); crosslinking the aggregated enzyme molecules to one another with a crosslinking agent (see col. 9, ln. 1-10).

In regards to claims 1-6, 9-12, Margolin teaches the crosslinking agent to be a combination of glutaraldehyde and a diaminoalkane (diaminooctane) (see col. 25, ln. 67, bridging col. 26, ln. 3).

In regards to claim 8, Margolin teaches the enzymes to be lipase, esterase, or protease (see col. 8, ln. 28-34).

In regards to claim 17, Margolin teaches the use of the crosslinking agent to crosslink a protein molecule to another protein molecule (see col. 5, ln. 35-37).

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In regards to claims 18-21, Margolin further teaches the enzyme crystals being combined with solid carrier materials (see col. 11, ln. 5-6, 25-26; col. 12, ln. 16-17). Although Margolin is silent with respect to the enzyme crystals being crosslinked with the carrier, since Margolin teaches the same enzyme crystals with the same crosslinking agent to the presently claimed invention, the reference's enzyme crystals would inherently be crosslinked to the carrier.

### Allowable Subject Matter

- 7. Claims 7 and 14-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 8. The following is a statement of reasons for the indication of allowable subject matter: no prior art has been found to teach, disclose, or fairly suggest a method of making crosslinked enzyme aggregates, the method comprising providing a crosslinking agent, wherein the crosslinking agent is prepared by combining a second compound and a first compound in a molar ratio of 10-1:1; in combination with all of the other limitations of claim 1.

### Response to Arguments

9. Applicant's arguments filed July 26, 2004 have been fully considered but they are not persuasive.

Throughout the Remarks, Applicants contend that in the presently claimed invention, the crosslinker is used as a spacer between enzyme molecules to from enzyme aggregates, whereas in the invention of Margolis, the enzyme crystals are obtained by crosslinking the crystals

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through one or more carbonhydrate moiteties on or through the amino acid side chain in the glycoprotein. However, the claim language does not include the use of the crosslinker as a spacer or the specific crosslinking in order to differentiate the presently claimed invention from the prior art. Thus, what Margolis teaches would read on the instant claims.

As pointed out by Applicants on page 8, 1<sup>st</sup> paragraph, of the Remarks and in paragraph 8 above, by choosing the proper ratio between the first and second compounds, a crosslinking agent would have the required length and thus spacing properties, to be patentably distinguish from the prior art.

#### Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thao T. Tran whose telephone number is 571-272-1080. The examiner can normally be reached on Monday-Friday, from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 20, 2004

James J. Seidleck Supervisory Patent Examiner Technology Center 1700